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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,738	12/09/2003	Brian K. Shoichet	7375	5161

22922 7590 05/11/2005

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EXAMINER

LEE, SUSANNAH E

ART UNIT PAPER NUMBER

1626

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,738

Applicant(s)

SHOICHET ET AL.

Examiner

Susannah Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 34 is/are rejected.
- 7) ☒ Claim(s) 30-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending in the instant application.

Priority

This application claims benefit of provisional application number 60/431,911 filed on 12/09/2002. The application names an inventor or inventors named in the prior application.

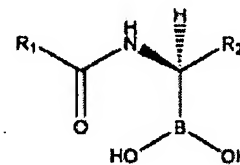
Response to Election/Restrictions

Applicant's election *without traverse* of Group I, Claims 28-34 in the reply filed on 04/25/2005 is acknowledged. Specially, the election of compound of the formula of Claim 28, wherein **R1** is a thiophen-2-yl moiety and **R2** is a phenyl moiety is acknowledged.

Scope of the Elected Invention

Claims 1-34 are pending in this application. Claims 28-34 have been elected for search and examination purposes.

The scope of the elected subject matter that will be examined and searched is as follows:



The pharmaceutical compositions of compounds having the formula, depicted in claim 28, page 66, line 7, wherein:

R1 is thiophen-2-yl, hydrogen, alkyl, alkenyl, cycloalkenyl or heterocyclyl;

R2 is phenyl, cycloalkenyl, alkenyl, alkyl, or heterocyclyl.

Scope of Withdrawn Subject Matter

Claims 1-27 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require

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separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

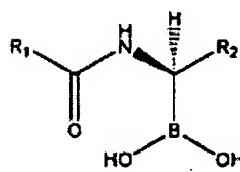
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al., "Structures of Ceftazidime and Its Transition-State Analogue in Complex with AmpC β -Lactamase: Implications for Resistance Mutations and Inhibitor Design," *Biochemistry*, 40, 9207-9214, published on web 07/10/2001.

Applicants instant elected invention teaches the compound having the formula,



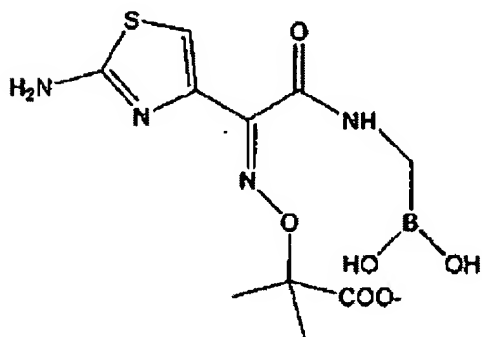
, depicted in claim 28, wherein R1 is thiophen-2-yl, hydrogen, alkyl, alkenyl, cycloalkenyl or heterocyclyl moieties and R2 is phenyl, cycloalkenyl, alkenyl, alkyl, or heterocyclyl

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moieties. These products are used as inhibitors of β -Lactamases. This is useful as antibiotics (claim 34, page 64).

Determination of the scope and content of the prior art (MPEP § 2141.01)

Powers teaches β -lactamase inhibitor compounds of formula,



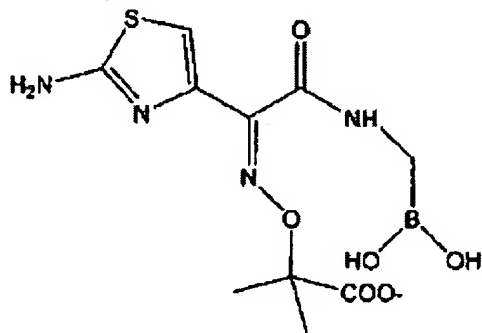
, a boronic acid inhibitor bearing the R1 side chain from cefazidime (See Powers et al., page 9208, Column 1, Compound B). These products can be used as antibiotics (See Powers et al., page 9211, Column 2, Discussion).

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Powers and the claims is that in the instant application there is a methyl group off carbon alpha to the boron, while in the prior art there is a hydrogen off the carbon alpha to the boron.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because the instantly claimed compound and the compound in Powers share the same boronic acid core



structure,

. The motivation to make the claimed

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compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Both the instantly claimed compounds and the compounds of Powers are used as β -lactamase inhibitors and are further used as antibiotics. Although, applicant's compound differs in that it has a methyl instead of a hydrogen group off the carbon alpha to the boron, it is well known in the art that hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137. In addition, Applicant's specification discloses the compound of Powers on page 15, Table 1, Compound 3. Finally, they are used for the same pharmacological use so one skilled in the art would expect the species would have similar properties as the genus.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term " β -lactam antibiotic" is not defined in the specification, claims or drawings. β -lactam antibiotics are a broad class of antibiotics including penicillin derivatives, cephalosporins, monobactams, carbapenems and β -lactamase inhibitors; basically any antibiotic agent, which contains a β -lactam nucleus in its molecular structure. A β -lactam is a lactam in which the amide bond is contained within a four-membered ring, which includes the amide nitrogen and the carbonyl carbon. A lactam is one of a series of anhydrides of an amido type, analogous to the lactones, as oxindol, a cyclic amide. They are the most widely used group of antibiotics available. Applicant is invited to point

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out where in the original specification, claims or drawings the term " β -lactam antibiotic" is defined. If a proper definition cannot be found, then applicant may obviate this rejection by deleting the term in the claim(s).

Objections

Claims 29-34 are objected to as being dependent upon a rejected base claim.

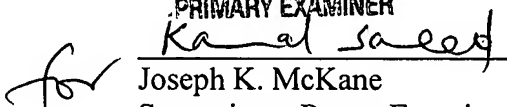
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Joseph K. McKane
Supervisory Patent Examiner
AU 1626
Date: 05/09/05